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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,624	11/07/2001	Girish J. Kotwal	032513-010	6917

21839 7590 05/03/2004

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EXAMINER	
MURPHY, JOSEPH F	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,624	KOTWAL ET AL.	
	Examiner	Art Unit	
	Joseph F Murphy	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *7-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-6 drawn to a method of treatment of Alzheimer's Disease by administration of the protein of SEQ ID NO: 1 in the response filed 2/27/2004 is acknowledged. The traversal is on the ground(s) that all the Groups make use of the protein of SEQ ID NO: 1. This is not found persuasive because CFR 1.475 (a) indicates that a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. CFR 1.475(e) indicates that the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim (MPEP 1893.03(d)). Since the common features do not establish an advance over the prior art (see the rejection under 35 USC § 103, *infra*), the inventions of Groups I-III do not form a single inventive concept within the meaning of Rule 13.2

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daly et al. (1998) in view of U.S. Patent No. 5,807,671 (Soreq et al.).

The claims are drawn to a method of treating Alzheimer's Disease (AD) by the administration of the protein of SEQ ID NO: 1, and also by the administration of the protein of SEQ ID NO: 1 in combination with cholinesterase inhibitors, or more specifically, acetylcholinesterase inhibitors. The claims are unpatentable because the Daly reference teaches that the A beta peptide can activate both the classical (antibody-independent) and alternate pathways of complement activation, and that the complement activation is due to the binding of A beta to the complement components C1q and C3, respectively, which initiate formation of the proinflammatory C5a and C5b-9 membrane attack complex (Daly at 624, Figure 4). Daly

teaches that the vaccinia virus complement control protein (with SEQ ID NO: 1), an inhibitor of both the classical and alternate pathway can down-regulate the biologically significant activation of complement by A beta, as demonstrated by an in vitro immunoassay (Daly at 625, Figure 6). Daly concludes that the therapeutic down-regulation of A beta-caused complement activation could greatly alleviate the progression of some of the chronic neurodegeneration characteristic of Alzheimer's disease.

The Daly reference does not teach the co-administration of cholinesterase or acetylcholinesterase inhibitors in conjunction with the administration of SEQ ID NO: 1 to treat AD. However, the '671 patent discloses that the principal current AD therapeutic approach, is the stimulation of the cholinergic system, and that the anti-ChE agent, physostigmine, has been shown to have a small, short-term positive effect on cognitive functions (column 5, lines 15-20). Additionally, the '671 patent discloses that the first anti-ChE drug to be approved for use in AD therapy in the US is Cognex (1,2,3,4-tetrahydro-9 aminoacridine, THA, tacrine), (column 5, lines 32-36). The '671 patent further discloses that synthetic versions, neostigmine and pyridostigmine have been made in order to enhance effectiveness or specificity, and that Neostigmine, one of many physostigmine derivatives, has increased stability and potency equal to or greater than physostigmine (column 3, lines 52-56). Therefore it would have been obvious to one of skill in the art at the time the invention was made to practice a method of treating Alzheimer's Disease (AD) by the administration of the amino acid of SEQ ID NO: 1, and also by the administration of the amino acid of SEQ ID NO: 1 in combination with cholinesterase inhibitors, or more specifically, acetylcholinesterase inhibitors, such as tacrine, neostigmine and pyridostigmine. The motivation is provided in the Daly reference, which teaches that the finding

that the vaccinia complement control protein can block complement activation by A beta peptide can be used in a combination therapy that could target any complement activation that would contribute to cellular influx and sustained chronic neurodegeneration of AD (Daly at 626).

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
April 22, 2004

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SUPERVISORY PATENT EXAMINER
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